

DEPARTMENT OF NEUROLOGICAL SURGERY

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Document Management Branch (HFA-305) Food & Drug Administration 5630 Fisher's Lane, Room 1061 Rockville, Maryland 20852 DOC: 97N-484S

Dear Sir:

As a neurosurgeon I felt I must comment on the FDA proposal to further regulate some types of allograft bone as "medical devices". If this is allowed to occur it can only be harmful to patient care. I believe the potential implications of FDA's regulatory action in this area are staggering. I do not believe that bone banks will have the expertise to participate in clinical trials, etc. and that this will only delay a much needed product from getting to the patient who needs it.

Please stay out of this area.' It is good that FDA regulates the safety of bone products but further FDA interference can only be harmful to good patient care.

Sincerely,

B. King Tipton, M.D.

BKT:PC

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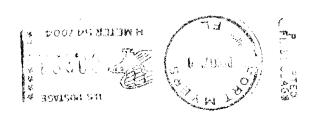
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